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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,110	12/07/2004	Javier Segado Ferran	250281.000	1427
54942	7590	12/11/2009		
Cozen O'Connor 250 PARK AVENUE NEW YORK, NY 10177			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 12/11/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto@cozen.com
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Office Action Summary

Application No.

10/517,110

Applicant(s)

FERRAN, JAVIER SEGADO

Examiner

HASAN S. AHMED

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

- Receipt is acknowledged of applicant's amendment, remarks, and RCE filed on 16 October 2009.
- The 35 USC 112 rejection of the previous Office action is withdrawn in view of the amendment.
- Applicants' remarks filed on 16 October 2009 have been considered but are moot in view of the new ground of rejection.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/12161 ("Martani") in view of S.T.P. Pharma Sciences 11 (3) 211-220, 2001 ("Mattsson") (cited in the IDS filed on 7 December 2004).

Martani teaches a tablet which disintegrates in the oral cavity within 30 seconds (see page 9, second full-paragraph) comprising:

- at least 60% mannitol (see page 11, third full-paragraph);
- active ingredient below 10% (see example 1);
- at least 30% microcrystalline cellulose (see page 11, third full-paragraph);
- 1-15% sodium croscarmellose (see paragraph bridging pages 11 and 12);

- 0.3-5% lubricant (*see* page 12, first full-paragraph); and
- a density of up to 1g/ml (*see* page 9, second full-paragraph).

Martani does not explicitly teach the claimed particle sizes, friability values, and proportion of insoluble elements, however, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine these values through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in particle sizes, friability values, and proportion of insoluble elements will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating the claimed values are critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from claimed values. Furthermore, since the prior art tablet demonstrates the same disintegration time as that being claimed, i.e. 30 seconds, and has the same ingredients (most of which are in overlapping or very close proportions), a person of ordinary skill in the art would expect that friability values, proportion of insoluble elements, and particle sizes would be similar between the prior art and the instant application.

Alternatively, Mattsson teaches a rapidly disintegrating tablet formulation comprising microcrystalline cellulose particles of less than 20 microns (*see* section 1.2) at a concentration of 20% (*see* section 3). Mattsson further teaches an active ingredient

(e.g. DCP) with particle size as low as 90 microns (see Table I). Regarding the disclosed 20% of microcrystalline cellulose, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05.

The process of spray-drying mannitol recited in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Martani explains that the disclosed tablet is beneficial for patients who have difficulty swallowing tablets (*see* page 1, third full-paragraph).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a fast disintegrating tablet comprising mannitol, active agent, microcrystalline cellulose, sodium croscarmellose, and a lubricant, as taught by Martani. One of ordinary skill in the art at the time the invention was made would have

been motivated to make such a tablet because it is beneficial for patients who have difficulty swallowing tablets, as explained by Martani.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615